

IN THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claim 1 (currently amended): A pharmaceutical aerosol formulation to be administered by a pressurized metered dose inhaler, which ~~comprises~~ consists of:

~~an active ingredient selected from the group consisting of~~ salmeterol, a stereoisomer thereof, ~~and or~~ a physiologically acceptable salt thereof, in solution in a propellant system, said propellant system comprising a liquefied HFA propellant, a co-solvent and 0 to 5% w/w water,

wherein said cosolvent is present in an amount which is no more than 35% w/w based on the total weight of said formulation, and

wherein said formulation has a pH of 2.5 to 5.5, and

wherein said pH of said formulation has been adjusted by addition of a mineral acid.

Claim 2 (currently amended): A pharmaceutical formulation according to claim 1, which ~~comprises~~ contains, as said cosolvent, at least one member selected from the group consisting of a lower alkyl (C1-C4) alcohol, a polyol, a polyalkylene glycol, a (poly)alkoxy alcohol, and mixtures thereof.

Claim 3 (currently amended): A pharmaceutical formulation according to claim 2, which ~~comprises~~ contains ethanol.

Claim 4 (previously presented): A pharmaceutical formulation according to claim 3, wherein said water is present in an amount of 0.5% to 5% w/w and said ethanol is present in an amount of no more than 25% w/w.

Claim 5 (previously presented): A pharmaceutical formulation according to claim 1, wherein said water is present in an amount up to 3% w/w.

Claim 6 (previously presented): A pharmaceutical formulation according to claim 1, wherein a fraction of particles equal to or less than 1.1 μm delivered on actuation of an inhaler, which contains said formulation, is higher than or equal to 30% as defined by the content of the stages S6-AF of an Andersen Cascade Impactor, relative to the content of the stages S3-AF of an Andersen Cascade Impactor.

Claim 7 (previously presented): A pharmaceutical formulation according to claim 1, wherein said fraction of particles equal to or less than 1.1 μm delivered on actuation of said inhaler is higher than 40%.

Claim 8 (currently amended): A pharmaceutical formulation according to claim 1, which ~~comprises~~ contains salmeterol xinafoate.

Claim 9 (currently amended): A pharmaceutical formulation according to claim 8, which ~~comprises~~ contains said salmeterol xinafoate in a concentration of 0.005 to 0.15% w/v.

Claims 10-11 (canceled).

Claim 12 (currently amended): A pharmaceutical formulation according to claim 1, which ~~comprises~~ contains one or more hydrofluoroalkanes selected from the group consisting of HFA 134a, HFA 227, and mixtures thereof.

Claim 13 (currently amended): A pharmaceutical formulation according to claim 1, which ~~comprises~~ contains 0.04% w/v salmeterol, 15% w/w ethanol, and 2% w/w water.

Claim 14 (previously presented): A pharmaceutical formulation according to claim 1, filled in a canister having part or all of its internal metallic surfaces made of standard aluminium, stainless steel, anodised aluminium or lined with an inert organic coating.

Claim 15 (canceled).

Claim 16 (currently amended): A method of preparing a pharmaceutical formulation according to claim 1, said method comprising:

- (a) preparing a solution of one or more active ingredients in one or more co-solvents;
- (b) adjusting the pH of said formulation to 2.5 to 5.5 by addition of a mineral acid;
- (c) optionally adding ~~a proper amount~~ 0 to 5% w/w of water ~~and adjusting the pH of the solution;~~
- (d) ~~(e)~~ filling a device with said solution;
- (e) ~~(d)~~ crimping said device with a valve and gassing; and
- (f) ~~(e)~~ adding a propellant containing a hydrofluoroalkane.

Claim 17 (currently amended): A method according to claim 16, wherein said device [[in]] is provided with a valve actuator whose orifice diameter is 0.22 mm.

Claim 18 (withdrawn): A method for the treatment of a respiratory disease, comprising administering an effective amount of a pharmaceutical formulation according to claim 1 to a subject in need thereof.

Claim 19 (withdrawn): A method according to claim 18, wherein said respiratory disease is asthma or chronic obstructive pulmonary disease.

Claim 20 (withdrawn): A method according to claim 19, wherein said respiratory disease is due to obstruction of peripheral airways as a result of inflammation or mucus hypersecretion.

Claim 21 (withdrawn): A method according to claim 18, wherein said respiratory disease is pulmonary edema or a surfactant-deficiency related disorder.

Claim 22 (withdrawn): A method according to claim 18, wherein said respiratory disease is acute lung injury or acute respiratory distress syndrome.